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COMPARE-1 CLINICAL TRIAL

PROTOCOL PRE-SPECIFIED INTERIM ANALYSIS OF FIRST 150 PATIENTS (COMPARE PILOT) AFTER 12-MONTHS OF FOLLOW-UP PRESENTED AT LINC 2018[1]

TRIAL DESIGN

WORLD'S FIRST Head-to-Head Prospective, **RANDOMIZED (1:1) CONTROLLED**
Trial comparing the lower dose Paclitaxel RANGER DCB (2 µg/mm²) to the higher dose Paclitaxel IN.PACT DCB (3.5 µg/mm²)

HYPOTHESIS

1. Lower dose Paclitaxel Ranger DCB (2 µg/mm²) with TransPax excipient is able to achieve similar patency as compared to the higher dose Paclitaxel IN.PACT DCB (3.5 µg/mm²) with Urea excipient
2. Post-procedure outcomes with the 0.018" Ranger DCB platform are similar to outcomes with the 0.035" and 0.018" IN.PACT DCB platform

• No statistically significant difference in patency between the higher dose Paclitaxel IN.PACT DCB and the lower dose Paclitaxel Ranger DCB (89% and 84%, respectively, p = 0.7).

• Ranger is loaded with 2 µg/mm² and IN.PACT is loaded with 3.5 µg/mm² of Paclitaxel

BASELINE CHARACTERISTICS AND RESULTS	Ranger™ (n=74)	IN.PACT™ (n=76)	p-value
Total Occlusions	39%	45%	0.5
Total Occlusion Length	111 mm	95 mm	0.5
Target Lesion Length	117 mm	122 mm	0.8
Moderate to Severe Calcification	58%	61%	0.7
Diabetics	34%	37%	0.7

[1]Results from the 150 patients from the pilot phase. Overall trial will enroll up to 414 patients.
*KM Estimate

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TRIAL DETAILS

OBJECTIVE:

To compare two different Paclitaxel coated balloons (with different coatings and different Paclitaxel dose density) in the treatment of high grade stenotic or occluded lesions in SFA and/or PPA in PAD patients with Rutherford class 2-4.

TRIAL DESIGN:

- Prospective, multicenter, randomized trial
- Randomization 1:1
- Phase 1: Pilot Study (150 patients)
- Phase 2: Extension (up to 414 patients) for testing of a formal non-inferiority hypothesis
- Stratification according to lesion length
- Follow-up clinical visits at 6, 12, 24 months

	Ranger™	IN.PACT™
Drug Dose	**2.0** µg/mm²	**3.5** µg/mm²
Longest Length Available	200 mm	150 mm
Platform	Sterling™	Admiral™ or Pacific™
Excipient	TransPax™	Urea

KEY ENROLLMENT CRITERIA:

- Rutherford 2, 3 or 4
- Stenotic, restenotic or occlusive lesions (≥70% stenosis) in the native non-stented SFA/PPA
- No prior treatment with drug coated balloons or drug-eluting stents in the treated limb
- Lesion ≤300 mm, RVD ≥ 4 mm and ≤ 6.5 mm

PRIMARY ENDPOINT DEFINITIONS:

Patency — Core lab adjudicated (12 months):
Efficacy: patency rate after one year defined as absence of clinically driven Target Lesion Revascularization (due to symptoms and drop of ABI of ≥ 20% or > 0.15 when compared to post-procedure) or restenosis with Peak Velocity Ratio > 2.4 evaluated by Duplex Ultrasound

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Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001.

CAUTION: Ranger is an Investigational Device. Limited by Federal (or US) law to investigational use only. Not available for sale.

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